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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/868,885	06/22/2001	Hirokazu Matsumoto	55999(46342)	7940

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EXAMINER	
BASI, NIRMAL SINGH	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 08/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/868,885	MATSUMOTO ET AL.	
	Examiner	Art Unit	
	Nirmal S. Basi	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *24 May 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1-3,6,10, 11 and 12* is/are pending in the application.

4a) Of the above claim(s) *12* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1-3, 6, 11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Response to restriction requirement filed 5/24/04 has been entered. Applicants have amended claims 1-3 and 6, cancelled claims 4-5 and 7-10, and added new claims 11 and 12. Newly added claim 11, directed to the elected invention of Group I will be examined.. Group I, claims 1-3, 6-10 are drawn to a oxytocin secretion regulator comprising a ligand peptide for a G protein coupled receptor, wherein the amino acid sequence for said ligand peptide represented by SEQ ID NO:44 is SEQ ID NO:3, 18 or 32, use of said ligand to regulate oxytocin secretion and use of ligand peptide to manufacture oxytocin secretion regulator. For the record it is noted, due to a typographical error, the restriction requirement mailed 10/3/03, accidentally included two Group IIs. In Applicants's response dated 11/3/03, Applicants clearly elected what should have been Group I. Since applicant has received an action on the merits for the originally presented invention (Group I), this invention has been constructively elected by original presentation for prosecution on the merits. Newly added claim 12 is drawn to a non-elected method for screening a compound regulating oxytocin secretion. Claims under examination are oxytocin secretion regulator (product), use of said ligand to regulate oxytocin secretion (first method of use) and use of ligand peptide to manufacture oxytocin secretion regulator (first method of making product). Claim 12 is directed to a second method of using the product, i.e. a screening method, which would be grouped separate to Group I. Accordingly, claim 12 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP

§ 821.03. A complete response to the final rejection must include cancellation of non-elected claims or other appropriate action (37 CFR 1.144) MPEP § 821.01. Claims 1-3, 6 and 11 are examined below.

2 The amendment filed 5/24/04 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: Claim 2 has been amended to include "has at least 80% identity to the amino acid sequence represented by SEQ ID NO:44.

Applicant is required to cancel the new matter in the reply to this Office Action.

Response to Applicants' Arguments

Applicants' arguments are addressed below:

Claim Rejection, 35 U.S.C. 112, second paragraph

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3, 6 and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 remains indefinite because the name oxytocin secretion regulator does not provide any structural limitations and the metes and bounds of the claim cannot be determined. Applicants argue Claim 1 been amended to identify the G protein-coupled receptor protein as phGR3. Applicants' arguments have been fully considered but are not found persuasive. It is still unclear what structure encompasses oxytocin secretion regulator. The claim recites no structure for the claimed compound, only a functional limitation. The metes and bounds of the compounds encompassed by the claim cannot be determined. It is suggested, to overcome the rejection, oxytocin secretion regulator be identified by SEQ ID NO.

Claim 6 remains indefinite because the names oxytocin secretion regulator and oxytocin secretion promoter do not provide any structural limitations and the metes and bounds of the claim cannot be determined. Applicants' argue, since the isolated and purified oxytocin secretion regulator has been structurally defined in the amended claim 1 the rejection should be withdrawn as it applies to claim 6. Applicants' arguments have been fully considered but are not found persuasive. It is still unclear what structure encompasses oxytocin secretion regulator or and oxytocin secretion promoter. The claim recites no structure for the claimed compound, only a functional limitation. The metes and bounds of the compounds encompassed by the claim cannot be determined. It is unclear what structure encompasses oxytocin secretion regulator and oxytocin secretion promoter. It is suggested, to overcome the rejection, oxytocin secretion regulator and oxytocin secretion promoter be identified by SEQ ID NO.

Claim 11 recites the limitation "the DNA" and "the polypeptide" in lines 3 and 4. There is insufficient antecedent basis for this limitation in the claim. Line two of the claim recites, "characterized by using a ligand peptide". It is not clear how the method for manufacturing the oxytocin secretion regulator is characterized by using a ligand peptide? Also, the claim is indefinite because the names oxytocin secretion regulator and ligand peptide do not provide any structural limitations, and the metes and bounds of the claim cannot be determined. The recited "DNA" also does not provide any additional information as to its encoded oxytocin secretion regulator. The claim recites no structure for the compound manufactured. The metes and bounds of the compounds manufactured by the claim cannot be determined. It is unclear what structure encompasses oxytocin secretion regulator and oxytocin secretion promoter. It is suggested, to overcome the rejection, oxytocin secretion regulator and oxytocin secretion promoter be identified by SEQ ID NO.

Claims 2 and 3 are rejected for depending on an indefinite claim.

Claim Rejection, 35 U.S.C. 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-3, 6 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated and purified oxytocin secretion regulator, comprising a ligand peptide which has the amino acid sequence represented by SEQ ID NO: 3, SEQ ID NO: 18, SEQ ID NO: 32 and SEQ ID NO: 44, or a salt thereof, for G protein-coupled receptors phGR3 and UHR-1, does not reasonably provide enablement for other oxytocin secretion regulators. Newly added claim 11 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for manufacturing an isolated and purified oxytocin secretion regulator, comprising culturing transformants containing specific DNA encoding the polypeptide sequence disclosed in SEQ ID NO: 3, SEQ ID NO: 18, SEQ ID NO: 32 and SEQ ID NO: 44 for G protein-coupled receptors phGR3 and UHR-1, does not reasonably provide enablement for manufacture of other oxytocin secretion regulators. The, specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The rejection of record (1/15/04) is applied to amended claims 1-3 and 6. Claim 11, the method for manufacturing ligand peptide of claim 1 is also rejected for the same reasons as those applied to claim 1.

Applicants' argue that the amendments obviate the rejection because the claims have been amended such that the oxytocin secretion regulator has been specified structurally and it's function is disclosed, and amply enabled by the specification. Applicants' arguments have been fully considered but are not found persuasive. The oxytocin secretion regulator has not been specified structurally in claims 1-2, 6 and 11.

Although, the function of the ligand peptide, being a regulator of G-protein-coupled receptor, phGR3, is disclosed, said function provides no information regarding the structure of said igand peptide. Even though, applicants have amended claim 2 to delete that the claimed ligand is, "the same or substantially the same as the amino acid sequence represented by SEQ ID NO:44", the newly added limitation, "has at least 80% identity to the amino acid sequence represented by SEQ ID NO:44" does not over come the rejection of record. The critical feature required for activity of claimed ligand peptide is contained in the PrRP polypeptide fragments encompassed by SEQ ID NO:3, SEQ ID NO:18, SEQ ID NO:32 and SEQ ID NO:44. There is no disclosure of other compounds, which contain the critical feature of the invention, which can be isolated or produced to function as claimed. The disclosure does not teach how to isolate, make and purify ligands other than those represented by SEQ ID NO: 3, SEQ ID NO: 18, SEQ ID NO: 32 and SEQ ID NO: 44, which interact with other unknown G protein coupled receptors and have oxytocin secretion regulator functions, without undue experimentation. SEQ ID NO:44 is a generic sequence of a polypeptide, which encompasses mutations that retain functionality of G-protein-coupled, phGP3, interaction. Apart form the variable regions contained in SEQ ID NO:44, which are represented by SEQ ID NOs: 3, 18 and 32, there is no disclosure of which amino acids contained in SEQ ID NO:44 can me changed or deleted to provide functional ligand peptide.

Therefore, claims 1-3 and 6, pertaining to ligand peptide, are rejected for reason given above and in the Office Action dated 1/15/04. Claim 11, the method for

manufacturing ligand peptide of claim 1 is also rejected for the same reasons as those applied to claim 1.

Claim Rejection, 35 U.S.C. 112, written description

5. Claims 1-2, 6 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 11 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The rejection of record (1/15/04) is applied to amended claims 1-2 and 6. Claim 11, the method for manufacturing ligand peptide of claim 1 is also rejected for the same reasons as those applied to claim 1. The instant specification does not contain a written description of the invention in such full, clear, concise, and exact terms or in sufficient detail that one skilled in the art can reasonably conclude that applicant had possession of the claimed invention at the time of filing.

Claims are drawn to:

a) Oxytocin secretion regulator/promoter, comprising a ligand peptide or a salt thereof, for G protein-coupled receptor protein

b) Oxytocin secretion regulator, of a) which has at least 80% identity to the amino acid sequence represented by SEQ ID NO: 44

c) Methods of manufacture a)

Applicants' argue that the within amendments obviate the rejection because the claims have been amended such that the oxytocin secretion regulator has been specified structurally and it's function is disclosed, and amply enabled by the specification. Applicants' arguments have been fully considered but are not found persuasive. The oxytocin secretion regulator has not been specified structurally in claims 1-2, 6 and 11. Although, the function of the ligand peptide, being a regulator of G-protein-coupled receptor, phGR3, is disclosed, said function provides no information regarding the structure of said igand peptide. Even though, applicants have amended claim 2 to delete that the claimed ligand is, "the same or substantially the same as the amino acid sequence represented by SEQ ID NO:44", the newly added limitation, "has at least 80% identity to the amino acid sequence represented by SEQ ID NO:44" does not over come the rejection of record. The critical feature required for activity of claimed ligand peptide is contained in the PrRP polypeptide fragments encompassed by SEQ ID NO:3, SEQ ID NO:18, SEQ ID NO:32 and SEQ ID NO:44. There is no disclosure of other compounds, which contain the critical feature of the invention, which can be isolated or produced to function as claimed.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-3 and 6 remain rejected, for reasons of record (1/15/04) under 35 U.S.C. 102(b) as being anticipated by Takeda Chemical Industries Ltd. (WO 97/24436, ref provided in previous Office Action).

Applicants argue Takeda does not disclose secretion and/or regulation of oxytocin secretion. Applicants argue, "In contrast, the present application provides a description of the relationship between oxytocin and the ligand throughout the specification; see also Example 2 and Figure 2. Additionally, the within amendments further define and clarify the features of the present invention, thereby further distinguishing the present invention from the cited reference". Applicants' arguments have been fully considered but are not found persuasive. Even though Takada does not disclose that relationship of ligand and oxytocin, the compounds disclosed by Tekada are 100% identical to those represented in by SEQ ID NOs:3, 8, 32 and 44, and inherently have the oxytocin secretion functionality. Takeda Chemical Industries Ltd. disclose an oxytocin secretion regulator, comprising a ligand peptide, or salt therof, for a G-protein-coupled receptor protein (inherent property of oxytocin secretion regulator), which has 100% sequence identity to SEQ ID NO:3, 18, 32 and 44 of instant application (see claim 2). Takeda Chemical Industries Ltd also disclose the use of a ligand peptide or salt thereof, for a G-protein-coupled receptor protein (inherent property of oxytocin secretion regulator). The disclosure of Takeda Chemical Industries Ltd meets the limitations of Claims 1-3 and 6, absent evidence to the contrary.

7. Claims 11 is rejected under 35 U.S.C. 102(b) as being anticipated by Takeda Chemical Industries Ltd. (WO 97/24436, ref provided in previous Office Action).

Takeda Chemical Industries Ltd. disclose an oxytocin secretion regulator, comprising a ligand peptide, or salt thereof, for a G-protein-coupled receptor protein (inherent property of oxytocin secretion regulator), which has 100% sequence identity to SEQ ID NO:3, 18, 32 and 44 of instant application. Takeda Chemical Industries Ltd also disclose the use of a ligand peptide or salt thereof, for a G-protein-coupled receptor protein (inherent property of oxytocin secretion regulator), for manufacture of an oxytocin secretion regulator (see claim 9). The disclosure of Takeda Chemical Industries Ltd meets the limitations of claims 11, absent evidence to the contrary.

8. No claim is allowed.

9 Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Normal S. Basic whose telephone number is 571-272-0868. The examiner can normally be reached on 9:00 AM-5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda G Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Art Unit 1646
August 4, 2004

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